

## **REMARKS**

Applicants thank the Examiner for the personal interview granted on January 20, 2004. As discussed in the interview, Applicants have previously presented experimental evidence, in the form of an affidavit pursuant to 37 C.F.R. § 1.132, demonstrating that the claimed percent bacterial filtration efficiency (%BFE) of the present invention is not an inherent characteristic of products made of the same or similar components as those used in the present invention, and specifically, that the product of U.S. Patent No. 6,156,677 to Brown Reed et al. ("Brown Reed") cited by the Examiner demonstrates a %BFE outside the range of Applicants' claimed invention. Applicants believe that they have established that, using the Brown Reed product as the closest prior art cited by the Examiner, the characteristic of %BFE is not inherent in polymer-impregnated paper-based webs. The Examiner agreed in the interview to reconsider the rejections under 35 U.S.C. § 102(b).

Applicants request that the Examiner reconsider the rejections of the claims in light of the following arguments and allow the pending claims.

- A. Rejection of claims 1-4 and 7-13 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Brown-Reed et al. (US 6,156,677); and rejection of claims 5, 6 and 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Brown-Reed et al. (US 6,156,677).**

The Examiner has maintained the rejection of claims 1-4 and 7-13 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Brown-Reed et al. (US 6,156,677), as well as the rejection of claims 5, 6 and 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Brown-Reed et al. (US 6,156,677).

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Therefore, the Brown Reed patent cannot anticipate the present invention unless the claimed %BFE is either stated in the Brown-Reed reference or inherent in the Brown Reed product.

There is no question that the Brown Reed patent does not set forth a stated %BFE. Accordingly, any anticipation by Brown Reed must be based on the %BFE inherent in the Brown Reed product.

Applicants have demonstrated through Karen Bean's previously submitted declaration, however, that the %BFE of the Brown Reed product is, in fact, outside the claimed %BFE range of the present invention. Despite the fact that the Brown Reed product comprises the same components as the present invention, Applicants have factually demonstrated that the %BFE is not inherent to the product. Thus, Brown Reed cannot anticipate the present claims and the § 102 rejection should be withdrawn.

With respect to obviousness, the Examiner states that the 92.45% BFE of the Brown Reed product is not significantly lower than the 95% claimed BFE of the present invention. Applicants respectfully disagree with the Examiner's conclusion. The use of the claimed product as a medical packaging substrate in sterilization processes necessarily requires that bacteria be kept outside the confines of the medical packaging. Therefore, Applicants contend that any increase in %BFE would decrease the level of bacterial infiltration, and would thus be significant.

In support of this contention, Applicants have submitted with this response a declaration under 37 C.F.R. § 1.132 executed by Dr. Jay Sommers, who is someone highly familiar with the field of medical packaging substrates. In the declaration, Dr. Sommers explains that the difference between the %BFE of the Brown Reed product and the claimed invention is important in the context of sterile environments. Dr. Sommers also clarifies that a product with a BFE of 92.45% allows 7.55% of the bacteria to penetrate, while a product with a BFE of 95% allows only 5% of the bacteria to penetrate, representing approximately a 30% reduction in the fraction of bacteria that can penetrate the product. Therefore, the %BFE of the present invention does represent a significant improvement over the %BFE of that found in the closest prior art.

In light of the above arguments and the submitted declaration, the Examiner is respectfully requested to withdraw the rejection of claims 1-4 and 7-13 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Brown-Reed et al. (US 6,156,677); and rejection of claims 5, 6 and 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Brown-Reed et al. (US 6,156,677).

**B. Rejection of various combinations of claims 1-20 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Isaac et al. (US 5,576,364), Bouchette (US 4,692,374), and Weber et al. (US 5,191,734).**

The Examiner rejected various combinations of claims 1-20 as anticipated by or as being obvious over Isaac, Bouchette, and Weber. The Examiner states that Isaac teaches a fibrous web saturated with a latex composition that is a blend of a water dispersible polymer and an elastomeric latex emulsion; that Bouchette teaches a fibrous web saturated with a latex composition that is a blend of two latex emulsions; and that Weber teaches a fibrous web saturated with a composition that is a combination of

solution polymer, synthetic polymer, and natural polymer. The Examiner concludes that because the products of Isaac, Bouchette, and Weber are made of the same material as the present invention, then the %BFE would be inherently present in the Isaac, Bouchette, and Weber products. Applicants have proven that this is not the case by previous submission of an affidavit pursuant to 37 C.F.R. § 1.132, that provides experimental data demonstrating that the product of Brown Reed, which is made of the same material as the claimed invention. The Examiner had previously stated that this declaration was irrelevant with respect to the %BFE of the Isaac, Bouchette, and Weber products.

However, Applicants demonstrated at the interview that the Brown Reed product does not inherently possess the %BFE claimed in the present application. This should confirm that one of skill in the art would not deem that the claimed %BFE would be necessarily present in similar products comprised of similar components, such as the products of Isaac, Bouchette, and Weber. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robinson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir 1999) (emphasis added). Therefore, Applicants believe that the §102(a) rejections over Isaac, Bouchette, and Weber have been overcome.

With respect to obviousness, it has been established by the declaration previously submitted by Applicants that the %BFE characteristic of polymer-

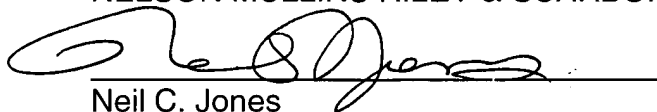
impregnated paper-based webs is not inherent. Therefore the products of the Isaac, Bouchette, and Weber patents would not render the claimed invention, which requires a specific %BFE, obvious.

Therefore, the Examiner is respectfully requested to withdraw the rejections of claims 1-20 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,576,364 to Isaac *et al*, U.S. Patent No. 4,692,374 to Bouchette, and U.S. Patent No. 5,191,734 to Weber *et al*.

In view of the foregoing arguments, we respectfully submit that the presently pending claims 1 - 13 and 15 - 20 are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application. We invite the Examiner to telephone the undersigned should any issues remain after the consideration of this response.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH



Neil C. Jones  
Registration No. 35,561  
Keenan Building, Third Floor  
1330 Lady Street  
Columbia, SC 29201  
Phone: (864) 250-2260  
Fax: (803) 256-7500

February 20, 2004  
Date